Legal
Legal framework: Yes
Authorizing legislation: Ministerial Decision No. 109/2008, Regarding the Issuance of the Regulations for Pre-qualification of Companies and Factories of Medical supplies to participate in the tenders of the Ministry of Health https://www.moh.gov.om/documents/71477/121151/Ministerial+Decision+English/91039f82-a220-4c65-8b2c-f82cf24ca0f6
Guidelines: N/A

National Regulatory Authority
National Regulatory Authority present: Yes
Name: Directorate General of Medical Supply, Ministry of Health https://www.moh.gov.om/ar/1
Responsibilities of the NRA: N/A

Medical device definition
Medical device defined: N/A
Text: N/A
In vitro diagnostic medical device (IVD) defined: N/A
Text: N/A

Medical device classification
Classification: N/A
Categories: N/A
Classification rules: N/A
Classification rules details: N/A

Essential principles
Essential principles: N/A
Details: N/A

Conformity assessment
Conformity assessment bodies: N/A
Details: N/A
Pre-marketing / procedure: N/A

Reliance
Reliance: Yes
Details: Medical devices in marketed in the country of origin or a developed country is eligible for pre-qualification
Jurisdictions: N/A

Clinical investigation
Clinical investigation controls: N/A
Details: N/A

Registration and listing
Registration of establishment: N/A
Details: N/A
Listing of medical devices: N/A
Details: N/A

Import controls
Import controls: N/A
Details: N/A
**Post market controls**

Post Market Surveillance: N/A
Details: N/A

Inspection (QMS): N/A
Details: N/A

Enforcement: N/A
Details: N/A

Adverse event reporting: N/A
Details: N/A

Field safety corrective action monitoring: N/A
Details: N/A

Advertising: N/A
Details: N/A

Labelling: N/A
Details: N/A

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Limitations: these data reflect a limited view and do not capture what may currently occur within Member States or how they implemented the data. Complete verification of the data may not be immediately possible and inaccuracies may linger. Mis-categorization or non-capture of a country’s regulatory framework is possible due to translation and interpretation.